

REMARKS/ARGUMENTS

The claims are 1-10. Claim 1 has been amended to recite the additional characteristic that the cuff leaves the upper ankle joint uncovered. In addition, claims 4-8 have been amended to improve their form, and new claims 9 and 10 have been added to recite the recitations previously appearing in claims 7 and 8, respectively. Support for the claims may be found, inter alia, in the disclosure in the paragraph bridging pages 1-2 and the first full paragraph of page 5. Reconsideration is expressly requested.

Claims 4 and 5 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for lacking proper antecedent basis for the term "the one" and for using the trademark "Velcro". In response, Applicants have amended claim 4 to replace the formulation "the one" with --a first side-- and "the other" with --a second-- for clarification purposes, and in claim 5, in addition to comparable changes, the term "Velcro" has been replaced with --hook and loop fastener--. It is respectfully submitted that the currently pending claims fully comply with 35 U.S.C. § 112, and Applicants respectfully request that the rejection on that basis be withdrawn.

Claims 1 and 6 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Wehr U.S. Patent No. 5,503,622* or *Mason et al U.S. Patent No. 4,938,777*. The remaining claims 2-5 and 7-8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Wehr* or *Mason et al* in view of *Epler et al U.S. Patent No. 5,135,473* or *French 2 607 383*. Essentially, the Examiner's position was (1) that each of *Wehr* and *Mason et al* disclose the orthosis cuff recited in the claims, (2) that *Epler et al* and the *French '383* references teach pads for an ankle wrap and (3) that it would have been obvious to one skilled in the art at the time the invention was made to provide the ankle bracelet of *Wehr* or *Mason et al* with a pad which can be located in the region of the tibiofibular joint, or with one or more closing elements.

This rejection is respectfully traversed.

As set forth in claim 1, as amended, Applicants' invention provides an orthosis cuff for the treatment or therapy of Ledderhose's disease or hypermobile foot joints, in which the tibiofibular syndesmosis is stabilized from the outside while maintaining the free mobility of the upper ankle. This arrangement reduces the movements between the distal ends of the tibia and the fibular and permits all other movements in the

upper ankle, as discussed on page 2, first full paragraph of the specification. Only by means of simultaneously stabilizing the fibulo-tibial syndesmosis and maintaining the other freedom of movement of the ankle is a relief of the symptoms of Ledderose disease achieved.

Neither *Wehr* nor *Mason et al.* discloses such an arrangement. As is evident from column 2, lines 1 to 8 of *Wehr*, the function of the cuff consists in exerting uniform pressure on the ankle which can be achieved only by completely covering the ankle by the cuff. As shown in FIG. 1 of *Wehr*, when the cuff is in place on the foot in the region of the ankle, approximately at 22, the cuff is completely closed.

In contrast, in Applicants' invention, the upper ankle joint is left uncovered, as discussed in the second full paragraph on page 6 of the specification, so that the mobility of the upper ankle joint and the Achilles tendon is not restricted. The molded parts 2a and 2b, shown for example in FIGS. 1 and 3, leave the Achilles tendon and the upper ankle free.

In addition, it is the task of the cuff, according to *Wehr*, to limit the inversion and eversion of the foot. See column 2,

lines 6 and 7 of *Wehr*. In contrast, with Applicants' cuff, this mobility of the foot is not intended to be restricted at all. As a result, the cuff according to *Wehr* gives a completely different freedom of movement to the foot than the cuff according to Applicants' invention. *Wehr's* cuff is entirely unsuitable for relieving the symptoms of Ledderhose disease or hypermobile ankles.

Similarly, the cuff according to *Mason et al.* is completely unsuitable for this purpose. Like *Wehr*, *Mason et al.'s* cuff attempts to prevent eversion and inversion of the foot and of course allows free dorsiflexion and plantar flexion. See column 2, lines 62, 63 of *Mason et al.* There is no disclosure or suggestion of an arrangement as in Applicants' cuff in which complete mobility of the ankle must be maintained which is required to relieve the symptoms of Ledderhose disease.

Just as important as complete mobility of the ankle is stabilization of the fibulo-tibial syndesmosis which is located anteriolaterally on the foot as shown with the number 5 in Figure 4 of Applicants' disclosure. In contrast, the cuff according to *Mason et al.* is open in this region. See Figures 1 and 3 of

Mason et al. As a result, the cuff arrangement according to *Mason et al.* cannot stabilize the fibulo-tibial syndesmosis.

The secondary references to *Epler et al.* and the FR '383 patent have been considered but are believed to be nor more relevant. Neither of these patents discloses or suggests an orthosis cuff made of stiff material surrounding the lower leg proximally of the upper ankle joint and leaving the upper ankle joint uncovered so that the mobility of the upper ankle joint and the Achilles tendon is not restricted and the tibiofibular syndesmosis is stabilized. Accordingly, it is respectfully submitted that the claims are patentable over the cited references.

With respect to the Examiner's request for Applicants to submit an English translation of *DE 3300111 A1* which was cited in the International Search Report, Applicants submit herewith a translation of the Preliminary International Examination Report from the European Patent Office together with an English language abstract for that patent. *DE 3300111 A1* relates to a clasp as is evident from FIG. 1 of that patent. In the applied state, this

clasp surrounds a large part of the back of the foot as well as of the subsequent ankle, which for that reason alone makes it not comparable with the orthosis cuff as set forth in Applicants' claim 1, as amended. In Applicants' cuff, the calf is surrounded proximally from the upper ankle and the back of the foot is intentionally left free. The lack of relevance of *DE 3300111 A1* has also been determined by the European Patent Office as set forth on page 5 of the translation of the Preliminary International Examination Report enclosed herewith. Although it is believed that this Search Report should have been sent to the U.S. Patent and Trademark Office by the International Office, as a precaution, Applicants are submitting a corresponding copy to complete the record. If the Examiner is still unconvinced of the irrelevance of the German reference, Applicants will submit a translation of this document.

In summary, claims 1 and 4-8 have been amended and new claims 9-10 have been added. In view of the foregoing, it is

respectfully requested that the claims be allowed and that this case be passed to issue.

Respectfully submitted,
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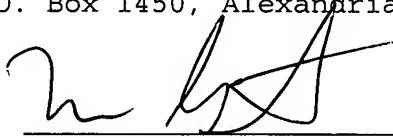
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Enclosure: Translation of Preliminary International Examination
Report and English language abstract of DE3300111A1

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